

REMARKS

A. Amendments

Support for the use of unroasted cocoa hulls can be found in Example 3.

Support for “fractionating” the cocoa oil can be found in Example 6.

Support for the oil comprising tocopherols can be found in original Claims 11 and 15 and for the tocopherols being tocopherols and tocotrienols can be found in original Claim 2.

B. §112 Rejection

Claims 2, 11, and 15-23 are rejected under 35 U.S.C. 112, second paragraph, as indefinite because Claim 2 depends from non-elected Claim 1, because in Claims 11 and 15 there is insufficient antecedent basis for the limitation “the phytosterols and tocopherols” in step (b), and because Claim 19 is not supported by the specification’s teachings. According to the Examiner, the phrase “purifying the cocoa oil by” the recited chromatographic means are not steps which would purify the oil, but instead appear to be analytical steps to assay the various components therein. The Examiner points to the discussion at pages 9-12. The Examiner notes that chromatographic steps of Claim 19 are outside the limitations of Claim 15 which is a process of extracting cocoa oil comprising phytosterols and tocopherols from cocoa hulls, not a process for obtaining various constituents from the cocoa oil. Accordingly, the Examiner strongly suggests that Claim 19 be canceled.

In view of the amendments of Claims 2, 11, 15, 19, and 21, as well as Claims 16-23 which depend on Claim 15, the rejections are overcome. It is clear from Example 6 that the cocoa hull oil can be subjected to liquid – solid chromatography to obtain various “fractions” containing components of different polarity. Hence, the word “fractionating” in Claim 19 is appropriate.

C. §102(b) Rejection

Claims 2 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by El-Saied et al. (Zeitschrift Fuer Erna., 1981), Baskakova et al. (SU 1734748 – DWPI Abstract), or Gavrilenko (Maslo-Zhir. Prom-st., 1977 – CAPLUS Abstract).

According to the Examiner, El-Saied et al. teach a fat which contains phytosterols such as those claimed which are obtained from cocoa shells via hexane extraction followed by evaporation of the hexane. The Examiner points out that, based upon chromatographic analyses, the cocoa shell fat was similar in composition to cocoa butter. The Examiner believes that cocoa oil obtained by hexane extraction would inherently comprise tocopherols and tocotrienols since hexane is disclosed to be a suitable solvent for extracting both the phytosterols and tocopherols. More importantly, the Examiner believes cocoa fat reads upon cocoa oil.

According to the Examiner, Baskakova et al. teach a cocoa husk (hull) oil which is added to a cosmetic formulation. The Examiner believes that this cocoa husk oil would inherently contain the claimed phytosterols and tocopherols since these are natural constituents of cocoa husk (hull) oil.

According to the Examiner, Gavrilenko teaches a cocoa husk oil which does not contain an extraction solvent. The Examiner believes that crude and refined cocoa husk oil would inherently contain the claimed phytosterols and tocopherols since these are natural constituents of cocoa husk oil.

The Examiner concludes that each of the cited references anticipates Claims 2 and 11.

D. Applicants' Response to §102(b) Rejection

El-Saied et al.

It is respectfully pointed out that "fat" does not read on "oil". According to Merriam Webster's Collegiate Dictionary, Tenth Edition "fat" is "a solid or semi-solid fat as distinguished from an oil". Hence, the Examiner's reliance on El-Saied et al. is not well founded. In addition, El-Saied's comparison of cocoa shell fat and cocoa butter showed differences in their physical and chemical properties (see Table 1), their stability (see Table 2), and more importantly sterol composition (see Table 5). There were also differences in the lipid classes and fatty acid composition.

Baskakova et al. and Gavrilenko

It is respectfully submitted that one cannot conclude from the limited teachings of these abstracts that the disclosed cocoa husk oils are the same as the claimed cocoa oil. The abstracts are silent regarding how the cocoa husks are obtained, how the cocoa oils are obtained, and more importantly, on the compounds present in the cocoa oil. The claimed cocoa oil comprises phytosterols, and tocopherols. No phytosterols or tocopherols are disclosed as being present in these cocoa oils. The fact that phytosterols and tocopherols may be present in cocoa husks does not mean they are necessarily present in cocoa oils obtained from the cocoa husks.

E. §102(b)/103(a) Rejection

Claims 2 and 11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Warocquier-Clerout et al. (Int. J. Cosmetic Sci., 1992).

According to the Examiner, Warocquier-Clerout et al. teach a lipid extract (which the Examiner believes reads upon an oil extract) termed ICSB of cocoa shell butter that is extracted

using solvents such as petroleum spirits (which the Examiner says is synonymous with petroleum ether). Based upon subsequent fractionation using silica gel column chromatography, the ICSB lipid extract was shown to contain various phytosterols as well as tocols.

The Examiner believes the cited reference discloses a cocoa oil extract that appears to be identical to that claimed since it was obtained using similar extraction solvent(s) and it was shown to contain the claimed compounds.

The Examiner states that even if the claimed cocoa oil is not identical because of some unidentified characteristics, the differences between that which is disclosed and that which is claimed are so slight that the lipid extract of the reference is likely to inherently possess the same characteristics as the claimed cocoa oil, particularly in view of the similar characteristics which they have been shown to share. The Examiner concludes that the claimed invention as a whole was at least *prima facie* obvious, if not anticipated, by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

The Examiner points out that this rejection under 35 U.S.C. 102(b)/103(a) is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). He notes that "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113.

F. Applicants' Response to §102(b)/§103(a) Rejection

It is respectfully submitted that Warocouier-Clerout article suffers from the same deficiency as the El-Saied article, i.e., it is directed to cocoa shell butter, not cocoa oil which El-Saied showed differed in sterol composition as well as physical and chemical properties. This

article cannot render the claimed cocoa oils obvious because oils are different from solid or semi-solid fats such as cocoa butter.

G. §103(a) Rejection

Claims 2, 11, and 15-23 are rejected under §103(a) as being obvious over El-Saied et al. (Zeitschrift Fuer Erna. 1981) and Warocquier-Clerout et al. (Int. J. Cosmetic Sci. 1992) in view of Mueller (J. Dairy Sci. 1959) and Alander et al. (WO 99/63031) and further in view of Newton (EP 0861600).

The primary references are relied upon for the reasons set forth above. The Examiner notes that neither primary reference expressly teaches grinding the cocoa hulls prior to extraction nor using some of the claimed extraction solvents.

According to the Examiner, Mueller teaches grinding cocoa shells prior to solvent extraction. The Examiner points out that grinding nuts and seeds prior to extraction is well known and facilitates the release of desired components during solvent extraction by maximizing surface exposure.

According to the Examiner, Alander et al. teach that oils such as cocoa butter extracted from various herbals contain phytosterols, tocopherols, and tocotrienols which can be effectively extracted using suitable solvents including nonpolar solvents such as hexane and petroleum ether.

The Examiner believes it would have been obvious to modify the extraction procedures taught by the primary references to make a cocoa oil extract by grinding the cocoa shells prior to solvent extraction based upon the teachings of Muller and to use and/or substitute other suitable extraction solvents such as petroleum ether based upon Alander et al.'s teachings regarding the equivalency of solvents for cocoa butter extraction since El-Saied et al. teach the similarity of

cocoa butter and cocoa shell fat. Hence, the Examiner believes that the skilled artisan would have a reasonable expectation of success in extracting cocoa shells using the solvents El-Saied et al. used to extract phytosterols as well as tocots.

The Examiner also believes it would also have been obvious to utilize micronized cocoa hulls as a starting material because Newton discloses that micronizing is a common means of breaking the outer husks/hulls of cocoa beans during processing. The Examiner deems the adjustment of particular conventional working conditions (e.g., removing the solvent by vacuum distillation, further exposing the extract to chromatographic techniques, and/or using hulls from particular types of cocoa beans) to be merely a matter of judicious selection and routine optimization well within the purview of the skilled artisan.

H. Applicants' Response to §103(a) Rejection

It is respectfully submitted that the teachings of the secondary references do not cure the deficiencies of El-Saied et al. or Warocquier-Clerout et al. which are directed to cocoa shell butter, not cocoa oil. A solid or semi-solid fat is not the same as a liquid oil and cocoa shell fat is not the same as cocoa oil.

Mueller does not teach grinding prior to extraction. Rather, Mueller teaches grinding cocoa hulls prior to their addition to butter oil for evaluation as an antioxidant. This would not suggest to one skilled in the art grinding cocoa hulls prior to solvent extraction.

With respect to the extraction solvents taught by Alander et al., that teaching is irrelevant because the lipid sample (which is cocoa butter, not cocoa oil) is extracted "after alkaline hydrolysis".

The relevance of Newton et al., who disclose the use of a micronizer to dry wetted grain or seed and gelatinize the starch in the grain or seed, is not clear. Such a teaching cannot render

obvious pretreating cocoa beans by infra-red heating to loosen the shells (hulls). See the discussion of the cocoa bean pretreatment in the specification.

I. Claims 7, 8, 20, and 21

It is respectfully submitted that these claims which are directed to non-roasted cocoa beans are not anticipated by or obvious over any of the cited references. In fact, El-Saied et al. teach away from using non-roasted cocoa hulls. It is taught at page 145 that "[u]sually cocoa beans are roasted at high temperature for a long period of time to remove the shell and the germ ...".

It is respectfully pointed out that Applicants' cocoa oils have much higher sterol levels when the cocoa oils are prepared by solvent extraction of unroasted cocoa hulls. The sterol increase was two-fold. See Example 4.

J. Closing

Withdrawal of the §112, §102(b), and §103(a) rejections and an early allowance of the amended claims is respectfully requested. No new matter is presented.

A marked-up version showing changes made to the claims is attached.

Respectfully submitted,

Date: February 4, 2003

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MARKED-UP VERSION SHOWING CHANGESB

2. (amended once) [The oil of Claim 1, wherein the oil further] A cocoa oil extracted from cocoa hulls which comprises [tocopherols, and tocotrienols] phytosterols and tocols.
3. (amended once) The oil of Claim [1] 2, wherein the phytosterols are campesterol, β -sitosterol, stigmasterol, cycloartenol, and 24-methylene cycloartanol.
4. (amended once) The oil of Claim [1] 2, wherein the phytosterols are a mixture of free and bound sterols.
7. (amended once) The oil of Claim [1] 2, wherein the cocoa hulls are from dried, unfermented or fermented, non roasted cocoa beans.
8. (amended once) The oil of Claim [1] 2, wherein the cocoa hulls are from micronized, non-roasted cocoa beans.
9. (amended once) The oil of Claim [1] 2, wherein the cocoa hulls are from roasted cocoa beans.
10. (amended once) The oil of Claim [1] 2, wherein the cocoa hulls are from Theobroma cacao.
11. (amended once) A cocoa oil which is prepared by a process comprising the steps of:
 - a) grinding cocoa hulls;
 - b) [treating] extracting the ground cocoa hulls with a solvent [which extracts the] that dissolves phytosterols and tocols;
 - c) removing the solvent; and
 - d) recovering the cocoa oil.
15. (amended once) A process for extracting a cocoa oil comprising phytosterols and tocols from cocoa hulls, which comprises the steps of:

a) grinding the cocoa hulls;
b) [treating] extracting the ground cocoa hulls with a solvent [which extracts the]
that dissolves the phytosterols and the tocols;

c) removing the solvent; and

d) recovering the cocoa oil.

19. (amended once) The process of Claim 15, further comprising the step of [purifying]
fractionating the cocoa oil by preparative high pressure liquid chromatography or column
chromatography.

21. (amended once) The process of Claim 15, wherein the cocoa hulls are from micronized,
unroasted cocoa beans.

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May 23, 1992

DERWENT-ACC-NO: 1993-157613

DERWENT-WEEK: 199319

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TITLE: Castor oil-based lipstick compsn. - contg. additional cocoa husk oil and
Convallaria, Angelica root and Origanum oil extract blend to prolong fixative action

INVENTOR: BASKAKOVA, N M; KONOVALCHIKOVA, N F ; OGILETS, M V

PATENT-ASSIGNEE: AEROZOL SCI PRODN ASSOC (AEROR), ELGAVA AREA STALGENE COLLECTIVE FARM
(ELGAR), SKIN VENERAL DISEASES RES INSTE FARM (SKINR)

PRIORITY-DATA: 1989SU-4761666 (November 21, 1989)

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
SU 1734748 A1	May 23, 1992		005	A61K007/027

APPLICATION-DATA:

PUB-NO	APPL-DATE	APPL-NO	DESCRIPTOR
SU 1734748A1	November 21, 1989	1989SU-4761666	

INT-CL (IPC): A61K 7/027

ABSTRACTED-PUB-NO: SU 1734748A

BASIC-ABSTRACT:

The lipstick compsn. contains the following ingredients (wt.%): perfume oil (6-9); ceresine (wax from ozokerite) (4-6); paraffin (6-8); sorbitan oleate (2-4); stearyl stearate (3-5); silicone oil (1-3); montan wax (4-7); confectionery oil (2-5); beeswax (4-7); lanolin (5-7); cacao husk oil (2-5); blend of Convallaria, Angelica root and Origanum oil extracts (2-5); dye (3-10); mother-of-pearl paste (20-28); perfume (1-2) and castor oil (balance).

USE/ADVANTAGE - For the cosmetic industry, a lipstick compsn. that ensures longer fixation of the prod. in conjunction with irritation-r elieving properties. Irritation is reduced due to the synergistic effect of the biologically-active components, which help soften the lips and hold the prod. in place. The presence of the plant extracts and fatty oils also produces a positive dermatological effect. Bul.19/23.5.9

ABSTRACTED-PUB-NO: SU 1734748A

EQUIVALENT-ABSTRACTS:

CHOSEN-DRAWING: Dwg.0/0

DERWENT-CLASS: A96 D21

CPI-CODES: A06-A00E3; A12-V04C; D08-B01;

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AN 1977:566283 CAPLUS

DN 87:166283

TI Treatment of cocoa husks at the Shuya Oil extraction Plant

AU Gavrilenko, I. V.

CS Vses. Nauchno-Issled. Inst. Zhirovoy Prom., Leningrad, USSR

SO Maslo-Zhir. Prom-st. (1977), (8), 36-7

CODEN: MZPYAE

DT Journal

LA Russian

AB Oil extd. from **cocoa husks** (contg. 5-10%

crude oil) is refined by washing with water at 10-15% by wt. at 60-70.degree. for 20-30 min, followed by neutralization with NaOH (200-50 g/L) at the same temp. The sepd. oil was washed twice with water in a vacuum app., sepd. again on a Westphalia separator, dried, and deodorized at 170-5.degree. at 3-5 mm Hg. The compn. of the oil from the husks was similar to that from cocoa beans but had a lower solidification point and hardness. C18:1, C18:0, and C16:0 were the main fatty acids of the **cocoa husk oil**. The oil quality did not change during 4 months of storage at 18-22.degree.. Cakes obtained as a byproduct of oil extn. had good physicochem. properties.